



Number:	Date:	Author:	Approved By:	Page(s):
UGAHRP-160-0	10/12/2018	HSO	IRB	Page 1 of 3

1. PURPOSE

1.1. The University of Georgia Human Subjects Office may charge a fee for IRB review of new **clinical trial** submissions that are supported by private or industry Sponsors. This practice of charging a fee is aligned with other academic institutions, and Private or Industry Sponsors of clinical research, specifically pharmaceutical and device companies, have generally considered the costs of IRB review as an integral part of a study's budget. The University of Georgia may also charge a fee for IRB review of research conducted by individuals who are not acting as agents of UGA. The fees will be used to offset some of the costs associated with review of clinical studies and enhance programmatic activities.

2. POLICY

- 2.1. The UGA IRB will charge a one-time initial review fee for clinical trials that meet **all** of the following criteria:
 - 2.1.1.study is supported or funded by a private or industry Sponsor;
 - 2.1.2.total budget of \$10,000 or more; and,
 - 2.1.3.reviewed by Full Board or Expedited procedure.
 - 2.2. The fee will not apply to clinical research that is: supported by Federal or State (including UGA) agencies, supported by private foundations and non-profit organizations; or investigator initiated single site studies.
 - 2.3. The UGA IRB will charge fees to unaffiliated institutions and/or individuals who are not acting as UGA agents for IRB determinations and reviews. These fees will be negotiated per institution as part of a reliance agreement or memorandum of understanding.
 - 2.4. The initial review fee is a one-time charge. Continuing reviews, modifications to an approved study, and other reviews (e.g., adverse events) are included in the initial review fee.
 - 2.5. Payment of this review fee for a clinical trial is considered a contractual obligation of the Sponsor.
 - 2.6. This fee is due and payable for any submission reviewed by the IRB even if the IRB disapproves the study, a research contract is not finalized, the study was withdrawn by the Sponsor or the Investigator, no participants were enrolled, or the study was never initiated.
 - 2.6.1.The payment of the fee does not guarantee IRB approval of the study protocol.
 - 2.7. If a disapproved study is resubmitted to the IRB for review, the applicable fee will be charged again.
 - 2.8. For clinical trial reviews, it is the responsibility of the PI and/or research personnel to notify the Sponsor of the review fees. In the event of non-payment by the Sponsor, the PI or the Department will be responsible for the fee.
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Number:	Date:	Author:	Approved By:	Page(s):
UGAHRP-160-0	10/12/2018	HSO	IRB	Page 2 of 3

- 2.9. For clinical trials that require an independent IRB (e.g., Western IRB) or when the UGA IRB does not have adequate expertise to review, a one-time fee for processing, and administrative review to facilitate submission and provide post-approval oversight will be charged.
- 2.10. When an IRB submission is received and is not designated initially as industry supported, but is later determined by the IRB to be industry supported, appropriate IRB fees will be assessed.
- 2.11. UGA's Institutional Official (IO) can alter or waive the fees for particular studies based on extenuating circumstances.
- 2.12. The fees are subject to change with approval by the IO.

3. PROCEDURES: Researchers

- 3.1. Investigators should communicate with the Sponsor that an IRB review fee is to be included as a separate line item in the contract budget. The fee is not considered as Facilities and Administrative Costs (i.e., Indirect/F&A) so it should be listed as a separate line item, and not included in the F&A calculation.
- 3.2. All initial study submissions in the UGA IRB portal must identify the funding source for the proposed research as well as include a copy of the contract.
- 3.3. All initial study submissions in the UGA IRB portal must describe the engagement of External Sites.
- 3.4. For research conducted by unaffiliated institutions or individuals who are not acting as agents of UGA, additional documentation and individual assurances may be required during the review process.
- 3.5. A written request for a waiver or alteration of fee with supporting explanation or justification should be sent to irb@uga.edu.

4. PROCEDURES: IRB Staff

- 4.1. The IRB Staff reviews the submission and confirms if this is an industry-sponsored clinical research with a budget of \$10,000 or more that will require Full Board or Expedited review.
- 4.2. The IRB Staff reviews the project and, if required, consults with the Office of Research Legal counsel to determine agency of the Principal Investigator.
- 4.3. The IRB Staff determines the review fee amount based on Appendix A: Fee Schedule, executes the institutional reliance agreement or memorandum of understanding, prepares an invoice, and sends it directly to the Sponsor or Institution (with a copy to the Principal Investigator) after review of a study.

5. MATERIALS

- 5.1. Appendix A: Fee Schedule.
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Number:	Date:	Author:	Approved By:	Page(s):
UGAHRP-160-0	10/12/2018	HSO	IRB	Page 3 of 3

6. REFERENCES

6.1. None.

UGAHRP-160-0

Appendix A. IRB Fee Schedule for Sponsored Clinical Studies

Service Rendered	Amount
Initial Full Board (Convened Meeting) Review	\$2500
Initial Expedited Review	\$1500
Reliance on an External IRB	\$1000